

KURZPROTOKOLL ATLAS

Öffentlicher Titel	Phase III Studie zu Apalutamid bei fortgeschrittenem Hochrisiko-Prostatakrebs
Wissenschaftl. Titel	A Randomized, Double-blind, Placebo-controlled Phase 3 Study of JNJ-56021927 in Subjects with High-risk, Localized or Locally Advanced Prostate Cancer Receiving Treatment with Primary Radiation Therapy
Kurztitel	ATLAS
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Krebserkrankungen der männlichen Geschlechtsorgane: Prostatakrebs - Erstlinie
Einschlusskriterien	- Age $\geq$ 18 years - Indicated and planned to receive primary radiation therapy for prostate cancer - Histologically confirmed adenocarcinoma of an intact prostate, and 1 of the following at diagnosis: 1) Gleason score $\geq$8 and $\geq$cT2c, 2) Gleason score $\geq$7, PSA $\geq$20 nanogram per milliliters (ng/mL), and $\geq$cT2c - Charlson index (CCI) $\leq$3 - An Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) grade of 0 or 1 - Adequate organ function: (1) aspartate aminotransferase (AST), alanine aminotransferase (ALT), within normal limits (WNL), (2) serum creatinine less than ($<$) 1.5 milligram/deciliter (mg/dL) ($<$133 micromoles/Liter [mcmol/L]), (3) platelets greater than or equal to ($\geq$)140,000/microLiter (mcL), independent of transfusion and/or growth factors within 3 months prior to randomization, (4) Hemoglobin $\geq$ 12.0 gram/deciliter (g/dL) (7.4 millimoles [mmol], independent of transfusion and/or growth factors within 3 months prior to randomization - Participants who are sexually active (even men with vasectomies) and willing to use a condom and agree not to donate sperm during the trial - Signed, written, informed consent - Be able to swallow whole study drug tablets
Ausschlusskriterien	- Presence of distant metastasis, (clinical stage M1). Isolated pelvic nodal disease below the iliac bifurcation (clinical stage N1) is not an exclusion. Diagnosis of distant metastasis (clinical M stage; M0 versus M1a, M1b, M1c) and pelvic nodal disease (clinical N stage; N1 versus N0) will be assessed by central radiological review. Patients are considered eligible only if the central radiological review confirms clinical stage M0. - Prior treatment with gonadotropin releasing hormone (GnRH) analogue or anti-androgen or both for $>$3 months prior to randomization - Bilateral orchiectomy - History of pelvic radiation - Prior systemic (example [e.g.], chemotherapy) or local (e.g. radical prostatectomy, cryotherapy) treatment for prostate cancer - History of seizure or any condition that may predispose to seizure (including, but not limited to prior stroke, transient ischemic attack or loss of consciousness $\leq$ 1 year prior to randomization; brain arteriovenous malformation; or intracranial masses such as schwannomas and meningiomas that are causing edema or mass effect) - Prior treatment with enzalutamide, abiraterone acetate, orteronel, galeterone, ketoconazole, aminoglutethimide, estrogens, megestrol acetate, and progestational agents (including cyproterone acetate) for prostate cancer - Prior treatment with radiopharmaceutical agents (e.g., strontium-89) or immunotherapy (e.g., sipuleucel-T) for prostate cancer

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- Prior treatment with systemic glucocorticoids ≤ 4 weeks prior to randomization or is expected to require long-term use of corticosteroids during the study
- Use of 5-alpha reductase inhibitors (e.g., dutasteride, finasteride) ≤ 4 weeks prior to randomization
- Use of any investigational agent ≤ 4 weeks prior to randomization
- Current chronic use of opioid analgesics for ≥ 3 weeks for oral or > 7 days for non-oral formulations
- Major surgery ≤ 4 weeks prior to randomization
- Current or prior treatment with anti-epileptic medications for the treatment of seizures
- Gastrointestinal conditions affecting absorption
- Known or suspected contraindications or hypersensitivity to apalutamide, bicalutamide or GnRH agonists or any of the components of the formulations
- Any condition for which, in the opinion of the investigator, participation would not be in the best interest of the subject

Alter	18 Jahre und älter
Sponsor	Janssen Research & Development
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02531516 EudraCT 2015-003007-38